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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: RP2 AAV-Based Gene Human Therapy for Ocular Diseases and Disorders Including XLRP

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to PTC Therapeutics GT, Inc. located in 100 Corporate, Middlesex Business Center, South Plainfield, NJ 07080**.**

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Hiba Alsaffar, Ph.D., Licensing and Patenting Manager at (240)-276-5530; or at E-mail: hiba.alsaffar@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

I. United States Provisional Patent Application No. 62/131,661 filed Mar. 11, 2015, [HHS Ref. No. E-050-2015-0-US-01];

II. International Patent Application No. PCT/US2016/022072 filed Mar. 11, 2015, [HHS Reference No. E-050-2015-0-PCT-03]; expired

III. Australian National Stage Patent Application No. 2016228751, filed Mar. 11, 2016, [HHS Ref. No. E-050-2015-0-AU-04]; pending

IV. Canadian National Stage Patent Application No. 2979229 filed Mar. 11, 2016, [HHS Ref. No. E-050-2015-0-CA-05]; pending

V. European national Stage Patent Application No. 1662623.3 filed Oct. 11, 2016, [HHS Ref. No. E-050-2015-0-EP-06]; issued (validated in DE, FR and GB)

VI. U.S. national Stage Patent Application No. 15/556,746 filed Sep. 8, 2017 [HHS Ref. No. E-050-2015-0-US-08]; issued

VII. Japanese National Stage Patent Application No. 2017-547425 filed Sep. 8, 2017 [HHS Ref. No. E-050-2015-0-JP-07]; pending

VIII. Divisional European Patent Application No. 20176667.2 filed May 26, 2020 [HHS Ref. No. E-050-2015-0-EP-13]; pending

IX. Divisional Japanese Patent Application No. 2020-167984 filed Oct. 2, 2020 [HHS Ref. No. E-050-2015-0-JP-14]; pending

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

"Development and commercialization of RP2 AAV-based gene human therapy for any ocular disease, disorder or condition, including human X-linked retinitis pigmentosa (XLRP)". This technology discloses Adeno-Associated Viral (AAV) vectors comprising nucleotide sequences encoding RP2 or RPGR- ORF 15 transgenes and their use in treating or preventing X-linked forms of retinitis pigmentosa (XLRP).

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated : July 2, 2021.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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